

**IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION**

**IN RE ANDROGEL ANTITRUST
LITIGATION (II)**

CASE NO. 1:09-MD-2084-TWT

**GEORGE STEVEN LEGRAND, on
behalf of himself and all others similarly
situated,**

CASE NO. 1:10-CV-2883-TWT

Plaintiff,

END-PAYOR CLASS ACTION

v.

**UNIMED PHARMACEUTICALS, INC.;
SOLVAY PHARMACEUTICALS, INC.;
WATSON PHARMACEUTICALS, INC.;
PAR PHARMACEUTICALS, INC.; and
PADDOCK LABORATORIES, INC.,**

Defendants.

**ANSWER OF DEFENDANTS ABBOTT PRODUCTS, INC. F/K/A SOLVAY
PHARMACEUTICALS, INC. AND UNIMED PHARMACEUTICALS, LLC
TO PLAINTIFF'S COMPLAINT**

Defendants Abbott Products, Inc. f/k/a Solvay Pharmaceuticals, Inc.
("Solvay")¹ and Unimed Pharmaceuticals, LLC² ("Unimed") (collectively,

¹ See Dkt. No. 68, *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-md-2084 (N.D. Ga.).

² The allegations in Plaintiff's Amended Complaint are all directed to Solvay, but Unimed is the party that prosecuted U.S. Patent No. 6,503,894 ("the '894 Patent") before the U.S. Patent Office, listed it on the FDA's Orange Book, and instituted the underlying patent litigation. The Amended Complaint also refers to

“Defendants”), by and through their attorneys, hereby submit their Answer in response to Plaintiff George Steven LeGrand’s (“Plaintiff”) Complaint in this matter. Defendants file their Answer subject to Plaintiff’s acknowledgment that any and all claims contained in Plaintiff’s Complaint, including claims pursued under California law, are subject to the Order issued by this Court on February 22, 2010, in which the Court held that “only the sham litigation claim survives” in all consolidated actions. *See* Dkt. No. 50 at 22, *In re Androgel Antitrust Litig. (No. II)*, No. 1:09-md-2084 (N.D. Ga.).

NATURE OF THE ACTION

1. Defendants admit that Solvay marketed AndroGel[®] “as a testosterone replacement therapy (‘TRT’) for males with a deficiency or absence of endogenous testosterone.” Defendants deny the remaining allegations in paragraph 1 of the Amended Class Action Complaint.

2. Defendants deny the allegations in paragraph 2.

3. Defendants deny the allegations in paragraph 3.

4. Defendants deny the allegations in paragraph 4.

5. Defendants deny the allegations in paragraph 5.

“Unimed Pharmaceuticals, Inc.,” but Unimed is an LLC. Accordingly, all references to Unimed are to Unimed Pharmaceuticals, LLC.

6. Defendants admit that “Brand name drugs and their generic versions contain the same active ingredient” but deny the rest of the allegations in paragraph 6.

7. Defendants deny the allegations in paragraph 7.

8. Defendants deny the allegations in paragraph 8.

9. Defendants deny the allegations in paragraph 9.

10. Defendants deny the allegations in paragraph 10.

JURISDICTION AND VENUE

11. Paragraph 11 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 11.

12. Paragraph 12 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 12.

13. Defendants admit that Solvay transacts business in this district and that venue is proper here. Otherwise, paragraph 13 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 13.

PARTIES

14. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 14, and therefore, deny the same.

15. Defendants deny the allegations in paragraph 15.

16. Defendants deny the allegations in paragraph 16.

17. Defendants deny the allegations in paragraph 17.

18. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 18, and therefore, deny the same.

19. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 19, and therefore, deny the same.

20. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 20, and therefore, deny the same.

BACKGROUND

The Regulatory System Governing Pharmaceuticals in the United States

A. New Drug Applications

21. Paragraph 21 describes legal rules to which no answer is required.

22. Paragraph 22 describes legal rules to which no answer is required.

23. Paragraph 23 describes legal rules to which no answer is required.

24. Paragraph 24 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 24.

25. Paragraph 25 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 25.

26. Defendants deny the allegations in paragraph 26.

27. Paragraph 27 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 27.

28. Paragraph 28 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 28.

B. Generic Drugs

29. Defendants admit that “Generic drugs are drugs that the FDA has found to be bioequivalent to their corresponding brand name drugs” but deny the rest of the allegations in paragraph 29.

30. Defendants deny the allegations in paragraph 30.

31. Paragraph 31 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 31.

32. Paragraph 32 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 32.

33. Paragraph 33 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 33.

34. Defendants deny the allegations in paragraph 34.

35. Paragraph 35 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 35.

36. Defendants deny the allegations in paragraph 36.

The Consumer Benefits Of Generic Drugs

37. Defendants deny the allegations in paragraph 37.

38. Paragraph 38 describes legal rules to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 38.

39. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 39, and therefore, deny the same.

DEFENDANTS' ANTICOMPETITIVE CONDUCT AND "SHAM"
LITIGATION

Solvay's Prosecution Of The '894 Patent

40. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 40.

41. Defendants admit the allegations in paragraph 41.

42. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 42.

43. Defendants deny the allegations in paragraph 43.

44. Defendants admit that United States Patent Application Serial No. 09/651,777 was filed with the PTO on August 30, 2000 and that United States Patent No. 6,503,894 issued from that application on January 7, 2003. Defendants deny the remaining allegations in paragraph 44.

45. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 45.

46. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 46.

47. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 47.

48. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 48.

49. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 49.

50. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 50.

51. Defendants deny the allegations in paragraph 51.

52. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 52.

53. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 53.

54. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 54.

55. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 55.

56. Defendants deny the allegations in paragraph 56.

57. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 57.

58. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 58.

59. Defendants admit that Unimed submitted the '894 Patent for listing in the Orange Book within 30 days of the Patent's issuance. Otherwise, paragraph 59 describes legal rules to which no answer is required. Defendants deny the remaining allegations in paragraph 59.

60. Defendants admit that, on or about June 12, 2003, Unimed requested a Certificate of Correction ("COC") for the '894 Patent. Defendants deny the remaining allegations in paragraph 60.

61. Defendants deny the allegations in paragraph 61.

62. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 62.

63. Defendants admit that the COC issued on December 16, 2003. Defendants deny the remaining allegations in paragraph 63 as the prosecution history of U.S. Patent No. 6,503,894 is publicly available and speaks for itself.

64. Defendants deny the allegations in paragraph 64.

65. Paragraph 65 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 65.

66. Defendants deny the allegations in paragraph 66.

Solvay Improperly Sues Generic Defendants For Infringement Of The '894 Patent

67. Defendants admit that Watson notified Solvay on July 7, 2003 that Watson had filed an ANDA containing a Paragraph IV certification. Defendants lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 67, and therefore, deny the same.

68. Defendants admit that, in August 2003, Unimed sued Watson for infringement of the '894 Patent.

69. Defendants admit that Paddock provided Solvay with the requisite notice that it filed an ANDA containing a Paragraph IV certification that the '894 patent was invalid, unenforceable, and/or not infringed by Paddock's ANDA. Defendants lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 69, and therefore, deny the same.

70. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 70, and therefore, deny the same.

71. Defendants admit that, in August 2003, Unimed sued Paddock for infringement of the '894 Patent.

72. Paragraph 72 describes a legal rule to which no answer is required. To the extent that an answer may be required, Defendants admit that Solvay and

Besins did not request additional information from the Generics beyond the detailed information provided in their Notice Letters.

73. Defendants deny the allegations in paragraph 73.

74. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 74, and therefore, deny the same.

75. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 75, and therefore, deny the same.

Solvay And Besins Put Their Scheme In Motion

76. Defendants deny the allegations in paragraph 76.

77. Defendants deny the allegations in paragraph 77.

78. Defendants deny the allegations in paragraph 78.

79. Paragraph 79 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 79.

80. Paragraph 80 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 80.

81. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 81.

82. Paragraph 82 states legal conclusions to which no answer is required and relies on publicly available documents, which speak for themselves. To the extent that an answer may be required, Defendants deny the allegations in paragraph 82.

83. Defendants deny the allegations in paragraph 83.

84. Paragraph 84 states legal rules and legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 84.

85. Defendants deny the allegations in paragraph 85.

86. Paragraph 86 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 86.

87. Paragraph 87 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 87.

88. To the extent that Plaintiff's allegations rely on the publicly-available prosecution history of U.S. Application No. 09/651,777, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 88.

89. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 89.

90. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 90.

91. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 91.

92. Defendants deny the allegations in paragraph 92.

93. Defendants deny the allegations in paragraph 93.

94. Defendants deny the allegations in paragraph 94.

Solvay's Settlement With Watson

95. To the extent that Plaintiff purports to represent certain aspects of an internal document and otherwise rely on publicly-available documents, those

documents speak for themselves. Defendants deny the remaining allegations in paragraph 95.

96. To the extent that Plaintiff purports to represent certain aspects of an internal document and otherwise rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 96.

97. To the extent that Plaintiff purports to represent certain aspects of an internal document and otherwise rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 97.

98. Defendants deny the allegations in paragraph 98.

99. Defendants deny the allegations in paragraph 99.

100. Defendants admit that Unimed, Besins, and Watson entered into a written settlement of the patent litigation. Defendants deny the remaining allegations in paragraph 100.

101. Defendants admit that Solvay, Unimed, and Watson Pharma, Inc. entered into a written co-promotion agreement, the terms of which speak for themselves. Defendants deny the remaining allegations in paragraph 101.

102. Defendants deny the allegations in paragraph 102.

103. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 103.

Solvay's Settlement With Par And Paddock

104. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 104, and therefore, deny the same.

105. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 105, and therefore, deny the same.

106. Defendants deny the allegations in paragraph 106.

107. Defendants deny the allegations in paragraph 107.

108. Defendants deny the allegations in paragraph 108.

109. Defendants deny the allegations in paragraph 109.

110. Defendants admit that Unimed, Besins, Par, and Paddock entered into a written settlement of the patent litigation, the terms of which speak for themselves. Defendants deny the remaining allegations in paragraph 110.

111. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 111, and therefore, deny the same.

112. Defendants deny the allegations in paragraph 112.

113. Defendants deny the allegations in paragraph 113.

114. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 114.

Solvay's Patent Was Unlikely To Prevent Generic Competition

115. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 115.

116. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 116.

117. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 117.

118. Defendants deny the allegations in paragraph 118.

119. Paragraph 119 states legal rules and legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 119.

120. To the extent that Plaintiff's allegations rely on publicly-available documents, those documents speak for themselves. Defendants deny the remaining allegations in paragraph 120.

121. Defendants deny the allegations in paragraph 121.

But For The Improper Patent Listing And "Sham" Litigation, Generic AndroGel Products Would Have Entered The Market

122. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 122, and therefore, deny the same.

123. Defendants deny the allegations in paragraph 123.

124. Defendants deny the allegations in paragraph 124.

125. Defendants deny the allegations in paragraph 125.

126. Paragraph 126 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 126. Defendants also lack knowledge or information sufficient to form a belief concerning the remaining allegations in paragraph 126, and therefore, deny the same.

CLASS ACTION ALLEGATIONS

127. Paragraph 127 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 127. Defendants also lack knowledge or information sufficient to form

a belief concerning the remaining allegations in paragraph 127, and therefore, deny the same.

128. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 128, and therefore, deny the same.

129. Defendants deny the allegations in paragraph 129.

130. Defendants deny the allegations in paragraph 130.

131. Defendants deny the allegations in paragraph 131.

132. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 132, and therefore, deny the same.

133. Defendants deny the allegations in paragraph 133.

134. Defendants lack knowledge or information sufficient to form a belief concerning the allegations in paragraph 134, and therefore, deny the same.

INTERSTATE TRADE AND COMMERCE

135. Defendants admit that AndroGel is sold in multiple states but deny the remaining allegations in paragraph 135.

136. Defendants deny the allegations in paragraph 136.

ANTICOMPETITIVE EFFECTS

137. Defendants deny the allegations in paragraph 137.

DAMAGES

138. Paragraph 138 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 138.

COUNT I

(FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR VIOLATIONS OF SECTION 1 OF THE SHERMAN ACT)

139. Defendants repeat and reassert all of the responses above and below as if fully set forth herein.

140. Defendants deny the allegations in paragraph 140.

141. Defendants deny the allegations in paragraph 141.

142. Defendants deny the allegations in paragraph 142.

143. Defendants deny the allegations in paragraph 143.

144. Defendants deny the allegations in paragraph 144.

145. Defendants deny the allegations in paragraph 145.

146. Defendants deny the allegations in paragraph 146.

COUNT II

FOR DECLARATORY AND INJUNCTIVE RELIEF UNDER SECTION 16 OF THE CLAYTON ACT FOR DEFENDANTS' VIOLATIONS OF SECTION 2 OF THE SHERMAN ACT

147. Defendants repeat and reassert all of the responses above and below as if fully set forth herein.

148. Defendants deny the allegations in paragraph 148.

149. Defendants deny the allegations in paragraph 149.

150. Defendants deny the allegations in paragraph 150.

151. Defendants deny the allegations in paragraph 151.

152. Paragraph 152 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 152.

153. Defendants deny the allegations in paragraph 153.

COUNT III

(Violation of the California Cartwright Act)

154. Defendants repeat and reassert all of the responses above and below as if fully set forth herein.

155. Defendants deny the allegations in paragraph 155.

156. Defendants deny the allegations in paragraph 156.

157. Defendants deny the allegations in paragraph 157.

158. Defendants deny the allegations in paragraph 158.

159. Defendants deny the allegations in paragraph 159.

160. Defendants deny the allegations in paragraph 160.

COUNT IV

(Violation of the California Unfair Competition Law)

161. Defendants repeat and reassert all of the responses above and below as if fully set forth herein.

162. Defendants deny the allegations in paragraph 162.

163. Paragraph 163 states legal conclusions to which no answer is required. To the extent that an answer may be required, Defendants deny the allegations in paragraph 163.

164. Defendants deny the allegations in paragraph 164.

165. Defendants deny the allegations in paragraph 165.

166. Defendants deny the allegations in paragraph 166.

167. Defendants deny the allegations in paragraph 167.

168. Defendants deny the allegations in paragraph 168.

169. Defendants deny the allegations in paragraph 169.

COUNT V

**(FOR RESTITUTION, DISGORGEMENT AND CONSTRUCTIVE TRUST
FOR UNJUST ENRICHMENT BY DEFENDANTS)**

170. Defendants repeat and reassert all of the responses above and below as if fully set forth herein.

171. Defendants deny the allegations in paragraph 171.

172. Defendants deny the allegations in paragraph 172.

JURY DEMAND

Plaintiff's Jury Demand states legal conclusions for which no response is required. To the extent that a response is required, Defendants deny the allegations.

PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to any relief whatsoever. Defendants deny each and every allegation of the Amended Complaint not specifically admitted.

Without assuming any burden that they would not otherwise bear, Defendants assert the following affirmative defenses:

AFFIRMATIVE DEFENSES

First Defense

The Amended Complaint fails to state a claim against Defendants for which relief can be granted.

Second Defense

Plaintiff's claims are barred, in whole or in part, because U.S. Patent No. 6,503,894 is valid, enforceable, and infringed by Watson's and Par/Paddock's respective generic testosterone gels.

Third Defense

Plaintiff's claims are barred, in whole or in part, because Defendants had a good-faith basis to initiate and maintain their patent infringement litigations against Watson and Paddock.

Fourth Defense

Plaintiff's claims are barred in whole because (1) under *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), and *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003), the exclusionary effect of Unimed's settlement agreements does not exceed the exclusionary scope of U.S. Patent No. 6,503,894, and (2) Defendants did not engage in sham litigation to enforce the patent or fraud on the Patent & Trademark Office in

procuring U.S. Patent No. 6,503,894. Unimed's settlements shortened, with certainty, by at least five years, the exclusionary scope of the patent (2020) and the settlements shortened by five and one-half years the exclusionary effect the regulatory regime has granted to Unimed and Besins for the marketing and sale of AndroGel[®] (2021). Because Defendant's alleged conduct did not exceed the scope of the '894 patent, Defendants are immune from liability under U.S. patent law.

Fifth Defense

Plaintiff's claims are barred, in whole or in part, by the applicable statute of limitations.

Sixth Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks standing to bring or maintain this action.

Seventh Defense

Plaintiff's claims are barred, in whole or in part, because Plaintiff has not suffered injury proximately caused by any conduct of Defendants and/or has not suffered, and will not suffer, injury of the type that the relevant statutes were designed to prevent.

Eighth Defense

Plaintiff's claims are barred because Defendants' actions were taken in good faith to advance legitimate business interests and had the effect of promoting, encouraging, and increasing competition.

Ninth Defense

Plaintiff's claims are barred, in whole or in part, because even assuming *arguendo* that the antitrust laws applied and further assuming *arguendo* that the alleged conduct had any potential anticompetitive effect, Defendants' settlement agreements are governed by the rule of reason and are lawful, as their procompetitive benefits outweigh any alleged anticompetitive effect.

Tenth Defense

Plaintiff's claims are barred, in whole or in part, because Defendants' conduct is protected under the *Noerr-Pennington* doctrine and under the Constitution of the United States.

Eleventh Defense

Plaintiff's claims are barred, in whole or in part, for failure to comply with the pleading requirements of Rules 8 and 9(b) of the Federal Rules of Civil Procedure.

Twelfth Defense

Plaintiff's claims are barred, in whole or in part, because the acts or omissions of Defendants did not substantially lessen competition in any properly defined market.

Thirteenth Defense

Plaintiff's claims are barred, in whole or in part, because Defendants do not maintain monopoly power in the relevant market.

Fourteenth Defense

Plaintiff's claims are barred, in whole or in part, because its alleged damages, if any, are speculative, and because of the impossibility of the ascertainment and allocation of those alleged damages.

Fifteenth Defense

Plaintiff's claims are barred, in whole or in part, because its alleged damages were neither caused in fact by Defendants, nor proximately caused by any action or conduct of Defendants.

Sixteenth Defense

Plaintiff's claims are barred, in whole or in part, because this action is not properly maintainable as a class action as alleged by Plaintiff.

Seventeenth Defense

Plaintiff's claims are barred in whole or in part by estoppel.

Eighteenth Defense

Plaintiff is barred from recovery of any damages because of and to the extent of its failure to mitigate any such damages.

Nineteenth Defense

Plaintiff's claims are precluded by the Federal Food, Drug, and Cosmetic Act, the Drug Price Competition and Patent Term Restoration Act of 1984, and related legislation.

Twentieth Defense

Plaintiff's claims are barred, in whole or in part, under the *Trinko* doctrine and its progeny because any harm to competition complained of stems from the intricate, multi-tiered regulatory regime which governs the production, sale, and manufacture of pharmaceutical products, including the Hatch-Waxman Act.

Twenty-First Defense

Defendants adopt by reference any applicable defense not expressly set forth herein that is pled by any other Defendant in this action.

Defendants reserve the right to amend this Answer or to assert other defenses as this action proceeds.

WHEREFORE, Defendants pray that judgment be entered dismissing the Amended Complaint with prejudice, together with costs, fees, and such other relief as may be just and proper.

Respectfully submitted, this 25th day of October, 2010.

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